

REMARKS

Claims 27-56 are active. Claim 27 tracks and finds support in original Claim 1. Part (3) of this claim has been amended to further describe the protein. Support for this amendment is found on page 11, first paragraph of the specification. Claims 28, 29, 30 and 31 track and find support in original Claims 3, 5, 7 and 9. Claim 32 also finds support in original Claim 9. Claim 33 tracks original Claim 11. Claims 34-36 find support in original Claim 9. Claims 37-40 find support in original Claim 13. Claims 41-48 find support in original Claim 1 and on page 11, first paragraph of the specification. Claims 49-56 find support in original Claims 23 and 25, Examples 1-7 of the specification and on page 34, last paragraph of the specification. Accordingly, the Applicants do not believe that any new matter has been added. Favorable consideration is requested.

The Applicants thank Examiner Cheu and SPE Le for the courteous and helpful interview of February 26, 2003. It was suggested that the Applicants further distinguish the complexes encompassed by the present claims from those of Ohbayashi et al., U.S. Patent No. 6,252,053. It was suggested that the open claim language in Claim 1 may allow this claim to encompass the complexes of Ohbayashi, where the protein (e.g. an antibody) is bound directly to the carrier. Accordingly, Claim 27, which tracks Claim 1, now indicates that in the carrier-enzyme-protein complexes of the invention that the protein is not conjugated directly to the carrier. As discussed, Claim 27 also further describes the protein determinant in the claimed complexes to address the indefiniteness rejection of Claim 1. Favorable consideration is now requested.

Specification/Abstract

The objection to the Abstract is moot in view of the substitute Abstract appended to this response.

Rejection—35 U.S.C. 112, second paragraph

Claims 1-26 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the cancellation of these claims. It would not apply to new independent Claim 27, which further describes the protein component of the present invention.

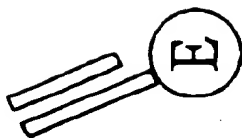
Rejection—35 U.S.C. 102

Claims 1-26 were rejected under 35 U.S.C. 102(a) as being anticipated by Ohbayashi et al., U.S. Patent No. 6,252,053. This rejection is moot in view of the cancellation of Claims 1-26. It would not apply to new independent Claim 27, because this claim is limited to carrier-enzyme-protein complexes wherein the protein is not directly conjugated to the carrier. The attached diagram (next page) compares (A) a conventional antibody-enzyme conjugate (no carrier) with (B) the complex of Ohbayashi and (C) the antibody-enzyme-carrier complex of the present invention. In Ohbayashi the protein (e.g. an antibody) is conjugated directly to the carrier, e.g. the antibody and enzyme are conjugated via a carrier, see col. 2, line 47. See also col. 5, lines 30-31 and lines 50-51, which describes leaving free amino groups on the carrier to which enzyme is bound, for subsequent binding of antibody to the same carrier. Claim 1 of Ohbayashi also refers to a similar process that results in conjugation of both the enzyme and antibody to the carrier. Thus, unlike the present invention where the antibody (or protein) is bound directly to the enzyme, the complexes of Ohbayashi et al. involve binding both the enzyme and antibody to the carrier. Accordingly, the Applicants respectfully request that this rejection now be withdrawn.

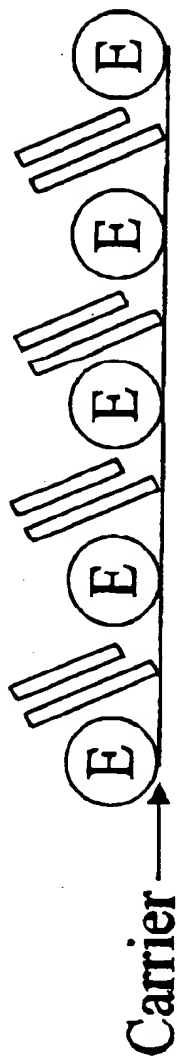
 : Antibody(Fab')

 : Enzyme

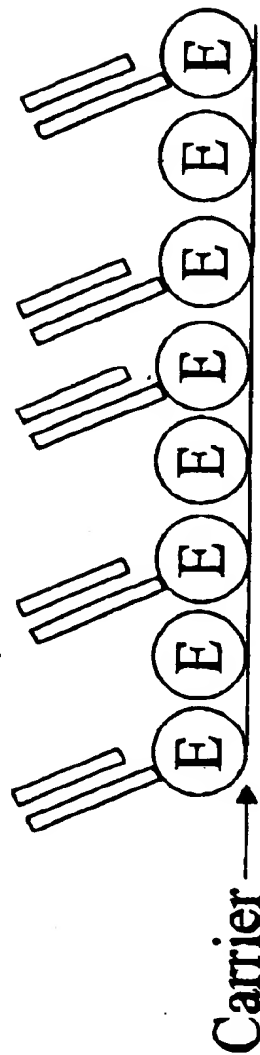
A) Conventional conjugate



B) Polymer based conjugate (USP6252053)



C) Our claim

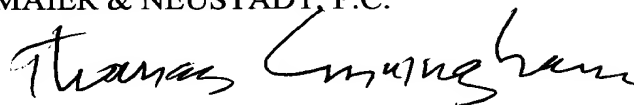


CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Norman F. Oblon
Attorney of Record
Registration No. 24,618

Thomas M. Cunningham
Registration No. 45,394



22850

Tel.: (703) 413-3000
Fax: (703) 413-2220
NFO:TMC:krs
I:\ATTY\TMC\2003-03\201001US-AMEND.DOC

Docket No.: 201001US0



Marked-Up Copy

Serial No: 09/740,903

Amendment Filed on: HEREWITH

IN THE SPECIFICATION

Please substitute the Abstract appended to this response for the Abstract which appears on page 39 of the specification.

IN THE CLAIMS

Cancel Claims 1-26.

Add new Claims 27-56.

--27-56. (New)—

a

ABSTRACT

A complex of a carrier, enzyme, and a protein that has a specific binding potency for a substance. This complex comprises a carrier, such as polylysine, that is conjugated to two or more molecules of an enzyme and comprises a protein, such an antibody, which is conjugated directly to the enzyme. These complexes are useful in immunoassays and enable highly sensitive and accurate assay of trace amounts of substances compared to conventional enzyme-antibody complexes. Products comprising such carrier-enzyme-protein complexes, such as immunoassay kits and methods for making such products.